

Lin v. MetLife

07 civ. 3218

EXHIBIT C

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF NEW YORK

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JEAN LIN,

Plaintiff,

-against- Index No:
07-CV-3218

METROPOLITAN LIFE INSURANCE COMPANY,

Defendant.

-----X

EXAMINATION BEFORE TRIAL of the
Defendant, DAVID CLAIN, M.D., taken by the
Plaintiff, held at the offices of Trief & Olk,
150 East 58th Street, 34th Floor, New York,
New York 10155, on May 28, 2008, at 10:05 a.m.,
before a Notary Public of the State of New
York.

1 D. Clain, M.D.

2 Dr. Kam's office records. The insurance papers
3 that Mr. Lin signed. Hospital records and
4 other doctor's records when he later developed
5 gastric cancer until the time of his death.

6 Dr. Aledort's report, if I didn't mention that
7 again. Those were main documents.

8 Q. By the way, did the gastric cancer have
9 anything to do with his hepatitis B?

10 A. No, I don't believe.

11 Q. So, his death was unrelated to any
12 hepatitis B?

13 MS. SHERER: Objection to the
14 form.

15 A. I think his gastric cancer was
16 unrelated. There was an issue which I noted in
17 my report about his development of severe liver
18 changes, you might say liver failure towards
19 the time of his death, as to whether that might
20 have been related to the hepatitis B.

21 Q. Did he die of gastric cancer?

22 A. I didn't know the answer to that.

23 Q. How much time did you spend in
24 preparation of the review of the materials and
25 the writing of the report?

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2 Q. If you have hepatitis B, there are
3 people who clear it themselves, correct?

4 A. Yes.

5 Q. There are people who get better through
6 treatment, correct?

7 A. Yes.

8 Q. There are people who don't get better,
9 correct?

10 A. Well, I'm not sure what you mean by that
11 last statement, "don't get better" in which
12 respect?

13 Q. That the treatment doesn't work, they
14 progress to cirrhosis and they could die.

15 A. Well, almost always the treatment works,
16 but they could still progress -- who have
17 progressed before they were treated to the
18 point of cirrhosis.

19 Q. Now, in this particular case, Mr. Lin
20 was successfully treated, correct?

21 A. Correct.

22 Q. There was absolutely no evidence of
23 cirrhosis, correct?

24 A. Correct.

25 Q. That, if it flared up again in the eyes

1 D. Clain, M.D.

2 I'm not referring to the case of Mr. Lin
3 and how Dr. Kam handled it. I'm just talking
4 in general.

5 Q. Do you disagree at all with the way
6 Dr. Kam handled Mr. Lin?

7 A. In terms of reading his record? If
8 there was a fellow of mine, I would heavily
9 critique what he had recorded. But if are
10 asking me, on the ground, do I agree that he
11 didn't need to re-treat Mr. Lin, if that's your
12 question, that is a different question.

13 Q. Well, let's start with: Did he need to
14 re-treat Mr. Lin?

15 A. No.

16 Q. You've got a chance, not only to look at
17 his records, but at his deposition, correct?

18 A. Yes.

19 Q. Let me hear your critiques about
20 Dr. Kam's treatment of Mr. Lin.

21 A. I don't think he recorded on paper what
22 he discussed with Mr. Lin. I don't think he
23 indicated that he ever educated him about
24 hepatitis B. There's nothing in there about
25 his family.

1 D. Clain, M.D.

2 There are a number of issues there,
3 which I record, I teach my training doctors to
4 record. I think it's extremely important that
5 everything you've done with the patient, what I
6 call treatment, is recorded at the time of the
7 visits.

8 Q. I understand that, but I'm asking you to
9 list all of those. I know you listed some.

10 Are there any others?

11 MS. SHERER: Objection to form.

12 A. Yes. Somewhere along the line, not
13 necessarily every time, that you indicate to
14 the patient what their risks are for the future
15 and what you're doing what you are doing such
16 as sonograms, measurement of tumor markers and
17 so on, the reason why you do those things.

18 Q. Anything else that you want to list as
19 part of your critique?

20 A. That would be a short list.

21 Q. I have plenty of time, so if you want to
22 take a minute to think about it and give me
23 some -- you can list anything else that you
24 might want to critique. I'll wait.

25 A. No, I think that, essentially, covers

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2 it.

3 Q. So, it sounds to me that all of the
4 critique was what was recorded, correct? There
5 is no critiquing beyond what was recorded?

6 A. I'm not critiquing the way in which he
7 prescribed medicines, no.

⁸ Q. Well, he only prescribed medicines -

9 A. Once

10 Q. -- for the interferon?

11 A Connect

12 Q. After that, no medicine was ever
13 prescribed?

14 A. Correct

15 Q. So, do you have any critique at all with
16 anything, other than recording what he said to
17 the patient?

18 A. No

19 Q. There are different things that were
20 being tested during Dr. Kam's treatment of
21 Mr. Lin, correct?

22 A. Yes

23 Q. What were the things that were being
24 tested?

25 A. So-called liver function tests. E

1 D. Clain, M.D.

2 antigen, E antibody. I think there may have
3 been a re-testing of surface antigens, several
4 tests of hepatitis viral DNA, a viral count,
5 so-called viral count.

6 I think he did a re-test of sonogram at
7 one point, a couple of times,
8 alpha-fetoprotein -- so-called A-F-P, which is
9 a tumor marker. Those were, essentially, what
10 he was doing.

11 Q. Now, the longer out you are from
12 successful treatment with interferon, does that
13 in any way indicate a likelihood of
14 reoccurrence or not?

15 A. I think the longer you're out and have
16 never flared, probably the risk is lower, but
17 that would be just my own gestalt. I'm not
18 sure that I'm quoting any scientific paper on
19 that.

20 Q. That word, "gestalt," it's not Zimbabwe?

21 A. It's German.

22 Q. Do you have any science to support your
23 opinion, or is it just when you're using
24 "gestalt" saying, it's my intuition?

25 A. No, I don't have a scientific paper.

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2 look for?

3 A. Yes.

4 Q. What were the results of the liver
5 function tests that Dr. Kam performed on
6 Mr. Lin?

7 A. They were normal.

8 Q. What does that show a doctor who's
9 treating a patient?

10 A. That the virus continues to replicate at
11 a relatively low level. In other words, the
12 treatment was successful.

13 Q. Why, if the virus is replicating at a
14 low level, do you still consider the treatment
15 to be successful?

16 A. We have limited goals in treating
17 hepatitis B, limited because we don't have
18 drugs that can eliminate the virus. So the aim
19 is to reduce viral activity to a level at which
20 there will not be ongoing damage to liver
21 cells, the consequence of which is, firstly,
22 the evolution of cirrhosis and, secondly,
23 because this will increase the risk of liver
24 cell cancer. So we want to keep the liver
25 without inflammation or hepatitis.

1 D. Clain, M.D.

2 Q. It's one of the number of factors,
3 correct?

4 A. Correct.

5 Q. What is surface antigen?

6 A. Surface antigen is really a piece of a
7 virus. So, the presence of surface antigen
8 indicates that there is virus circulating.

9 These are parts of the virus that are being
10 antigenically tested.

11 Q. What is the purpose of testing viral
12 DNA?

13 A. Viral DNA is a count of the viruses
14 using a technique called PCR, actual counts of
15 the number of viruses that's evolved. People,
16 back in history, didn't have PCR's, but it
17 since, historically, has changed, but,
18 basically, to answer your question, it's a
19 viral count.

20 Q. What is the protein alpha-feta that you
21 indicated?

22 A. Alpha-fetaprotein is a marker that as --
23 of which -- a whole category of markers that
24 are produced by various tumors.

25 Alpha-fetaprotein outside pregnancy,

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2 where it is normal, is produced by only one or
3 two tumors, one of which is liver cell cancer.

4 And so, its presence in the serum outside of
5 pregnancy, if it was much elevated, indicate
6 the patient probably has liver cell cancer.

7 Q. That was negative when tested for
8 Mr. Lin?

9 A. Yes.

10 Q. What tests do you, Dr. Clain, rely on in
11 determining whether hepatitis B needs treatment
12 and is active? All of them, some of them, none
13 of them?

14 A. Let me just get a recap of that. What
15 tests do I do?

16 Q. I don't care whether you do it or
17 someone else does it, but what tests do you
18 rely on, as a physician, in determining whether
19 hepatitis B needs to be treated and/or in the
20 inactive stage?

21 A. So, first of all, I'd have to -- you'd
22 have to know they have hepatitis B, surface
23 antigen, you do E antigen and E antibody and
24 liver function profile, mainly for the
25 transaminases. And in cases where there is not

1 D. Clain, M.D.

2 A. An additional zero, a long change.

3 Q. So, from a hundred to a thousand?

4 A. Yes.

5 Q. Or from a thousand to 10,000?

6 A. Correct. From 120 to 250 is

7 meaningless.

8 Q. Or from 300 to 500 is meaningless?

9 A. Yes.

10 Q. If you go to Page 3 of your report and
11 go to the very first paragraph, do you see the
12 sentence beginning, "He achieved"?

13 A. Yes.

14 Q. Could you read that one sentence into
15 the record.

16 A. "He achieved the primary goals of
17 therapy, which are suppression of hepatitis B
18 viral DNA" -- in quotes -- "viral count,
19 normalization of liver enzymes, AST and ALT and
20 seroconversion to HBeAg-negative."

21 Q. What do you mean by "suppression of the
22 hep B viral DNA"?

23 A. That the count came way down from what
24 it was.

25 Q. What does the word "suppression" mean,

1 D. Clain, M.D.

2 just way down?

3 A. Yes, because that's all we can achieve
4 as a goal.

5 Q. So, he achieved the most he could have
6 achieved? Is that what you are saying?

7 MS. SHERER: Objection to the
8 form.

9 A. Yes.

10 Q. The liver enzymes were normal, correct?
11 So, you wouldn't get anything, other than
12 normal; that's the best you can do, correct?

13 A. Right.

14 Q. The seroconversion to HBeAg-negative,
15 that's the best you can do also, correct?

16 A. Correct.

17 Q. So, he achieved the best he could do by
18 the treatment he gave?

19 A. Yes. As I stated there, he achieved the
20 primary goals of therapy.

21 Q. Do you mean by "primary goals," meaning
22 that he achieved all the goals of therapy or
23 just some of the goals?

24 A. I guess he achieved all the goals of
25 treatment with interferon, yes.

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2 question I'm asking assumes that everybody has
3 been treated.

⁴ A. There's no data. There is no data.

5 Q. But I'm not talking about --

6 A. If you're talking about the follow-up of
7 the incidents of cancer in various categories,
8 you know, with and without cirrhosis, you
9 know --

10 Q. Is there any data comparing the
11 treatment of patients who have been
12 successfully treated with -- for hepatitis B
13 and do not have cirrhosis and never had
14 cirrhosis with the general public's incidents
15 of cancer?

16 A. Yes, there is data on that.

17 Q. Where is that data?

18 A. In what paper?

19 Q. In what paper.

²⁰ A. I can't quote you the paper offhand, no.

21 Q. I've looked at the papers that you've
22 referred to, and all of those papers included
23 in their study people who had cirrhosis,
24 correct?

25 A. I don't know about that

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2 treated and so on, all of which are confining
3 factors in the incidents of liver cell cancer.

4 (Whereupon, the referred to
5 place was read back by the Reporter.)

6 MR. TRIEF: I move to strike the
7 part that's not responsive.

8 MS. SHERER: I move to renew.

9 MR. TRIEF: Off the record.

10 (Whereupon, an off-the-record
11 discussion was held.)

12 Q. What is the incidence of liver cancer in
13 the general public?

14 A. I don't have a number.

15 Q. Approximately.

16 A. It's very low.

17 Q. Tell me.

18 A. I don't know.

19 Q. One in a million, one in a thousand, one
20 in a hundred?

21 A. I don't know. I don't know the number.

22 Q. What is the incidence rate of liver
23 cancer for those who have been successfully
24 treated for hepatitis B without cirrhosis?

25 A. It's a few times increased, like three

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times increased. It varies in different populations, in different places. It isn't the same here and there. It depends on where the study was done, and there aren't that many studies.

7 But there is a severalfold increase in
8 liver cancer. I can refer you -- and I refer
9 to that, I think, in one of my comments in the
10 report, is that, if you look at the AASLD
11 Guidelines on the hepatocellular cancer, they
12 actually quote your papers based on their Asian
13 patients who are not cirrhotic, have no
14 activity, either treated or untreated, are
15 inactive, have an increased instance of
16 hepatocellular carcinoma.

17 They quote three or four papers. If you
18 look at this AASLD Guidelines, they're quoted
19 here, and they're listed in the paper.

20 MS. SHERER: Should we mark that
as an exhibit?

MR. TRIEF: Sure.

23 A. If you look in the guidelines -- this is
24 the hepatocellular carcinoma guidelines, not
25 the hepatitis B guidelines. Hepatitis B on

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2 Does it say that anywhere? I mean, is
3 there something that says that?

4 A. I think there's something that says
5 that. When you get back to Page 1210,
6 "Similarly, the risk of hepatocellular
7 carcinoma" -- "Similarly, the risk of
8 hepatocellular cancer persists in long-term
9 hepatitis B carriers from Asia" -- oh, sorry.

10 I retract. I'm reading the wrong sentence.

11 Q. The question goes back to the fact that
12 there isn't any comparison in this study of any
13 patients who were successfully treated --

14 A. No, not successful treatment.

15 Q. You have to wait for me to finish.

16 A. Sorry.

17 Q. You would agree that there isn't
18 anything in this study that refers at all to an
19 analysis of what the incidence is of liver cell
20 cancer for patients who have been successfully
21 treated for hepatitis B, correct?

22 A. Not in these studies, no.

23 Q. Liver cancer in the general public, from
24 an instance level, is extraordinarily low, is
25 it not?

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2 A. Very low.

3 Q. When you are looking at mortality rates,
4 you are looking at other types of cancers and
5 heart disease and things of that nature,
6 correct?

7 MS. SHERER: Objection to the
8 form.

9 A. Yes.

10 Q. The effect of liver cell cancer, because
11 its incidence is so low on mortality rate, is
12 insignificant; wouldn't you agree?

13 MS. SHERER: Objection to form.

14 A. No, I wouldn't agree. It's not
15 insignificant for that group of patients. It's
16 very significant.

17 Q. Obviously, someone who gets liver cell
18 cancer, it is significant for that person. I
19 am talking about, in order to analyze the
20 overall mortality rate of a group of people,
21 liver cell cancer is such a small incidence,
22 that it is insignificant in making that
23 analysis, correct?

24 MS. SHERER: Objection to form.

25 A. No, that's not true. Liver cell cancer

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2 A. No, it's not on the bottom of the list,
3 but I can't tell you exactly where it is on the
4 list.

5 Q. Would you agree that, in looking at the
6 overall mortality rate in the United States,
7 liver cancer is a very low component?

8 MS. SHERER: Objection.

9 A. I would prefer to answer that question
10 in a different way.

11 Q. Could you answer it that way?

12 A. No, because we're talking here about
13 Asian patients born in Asia, and that's a very
14 different question. The incidents of liver
15 cancer dates in this country from immigrant
16 Asian males is significant.

17 Q. What is significant --

18 A. I can't give you a number, but it's a
19 very --

20 Q. Approximately.

21 A. I don't have numbers. I don't keep
22 those kind of numbers in my head. I can't give
23 you a number.

24 Q. In order to say "significant," wouldn't
25 you have to have some approximation?

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2 MS. SHERER: Objection to the
3 form.

4 A. No, I don't need to do that. I can tell
5 you that, just from seeing the patients in my
6 own experience, practice, how often I have seen
7 patients dying of liver cancer.

8 Q. Isn't that anecdotal?

9 MS. SHERER: Objection to the
10 form.

11 A. It may be anecdotal, but it's very
12 significant.

¹³ Q. You wouldn't, as a scientist, accept
¹⁴ anecdotal information, would you?

15 MS. SHERER: Objection to the
16 form.

¹⁷ A. I'm simply indicating to you that I know
¹⁸ the number is, you know, significant, but I
¹⁹ can't quote you the number.

²⁰ Q. I'm not asking for a quote. I'm asking
²¹ for any kind of approximation

22 MS. SHERER: Objection to the
23 form

²⁴ A. I can't give you a number.

²⁵ Q. Is it fair to say that the basis of your

1 D. Clain, M.D.

2 United States who were immigrants have active
3 disease?

4 A. Yes, in recent studies in New York City,
5 for example.

6 Q. What percentage of them have been
7 infected?

10 Q. What percentage of Caucasians in the
11 United States have been infected, at one time,
12 with hepatitis B?

13 A. It varies widely, you know. In other
14 words, it depends on what risk group you fall
15 into.

16 Q. The overall population.

17 A. Well, studies don't do overall
18 population because there are great population
19 studies in the United States. It depends on
20 how you selected the people you are testing,
21 you understand.

22 So, probably you are talking about
23 something like seven or eight -- 7 percent or
24 6 percent of people -- and I'm hesitating a
25 guess -- have been exposed to hepatitis B.

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2 And a small percent, somewhere under
3 1 percent -- well under 1 percent -- probably
4 point something percent have active disease.

5 Q. So something significantly under
6 1 percent of the Caucasians have what you
7 define as active disease?

8 A. Yes.

9 Q. Fifteen to 20 percent of Asians who
10 immigrated here have active disease?

11 A. Yes.

12 Q. What is the highest risk group as it
13 relates to hepatitis B in developing liver
14 cancer?

15 A. Asian men who have active disease who've
16 gone on to develop cirrhosis and have never
17 been treated would be the very highest group.

18 Q. That was not Mr. Lin?

19 A. No.

20 Q. So, if you go to Page 4 of your report
21 and you go down to the last paragraph on
22 Page 4 -- it's an incomplete paragraph, but
23 it's the last paragraph, nonetheless -- do you
24 see what you have in bold print?

25 A. Right.

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2 maybe 10 percent. I wouldn't consider that a
3 large number.

4 Q. So, it's how you define the word
5 "large"?

6 A. Yes.

7 Q. That was your disagreement with
8 Dr. Aledort?

9 A. Yes. A large number would have to be a
10 substantial percent, but it isn't.

11 Q. Then, after that reference, you indicate
12 that, children become chronic carriers with all
13 the long-term risks of liver damage and liver
14 cell cancer and that's because they're not
15 treated in Asia, correct?

16 That's the point you're making?

17 A. I'm not making a point that they're not
18 treated, but anyone who's chronically infected
19 has those risks.

20 Q. It's because they've developed
21 cirrhosis, correct?

22 A. In terms of evolving to liver damage, if
23 they're treated before that, yes, you can
24 prevent that. But we don't know what the
25 effect is of treatment in preventing liver

1 D. Clain, M.D.

2 cancer.

3 Q. The sentence there is assuming, though,
4 that these children in Asia are not being
5 treated; am I correct?

6 Is that your assumption on Page 5?

7 A. All I'm saying is, if you become a
8 chronic carrier, these are your risks. I am
9 not implying treatment or no treatment. Once
10 you get into a chronic situation, these are the
11 risks. Now, obviously, any competent physician
12 would intervene, but that's not my point. Once
13 you develop hepatitis B, these are the risks in
14 front of you.

15 Q. Why would you intervene if the
16 intervention doesn't do anything for the
17 patient?

18 A. How do you mean? I don't understand the
19 question.

20 Q. My apologies.

21 Doesn't the intervention help the
22 patient, and isn't its purpose to help the
23 patient?

24 A. I think we're talking at cross purposes
25 here. That statement was made simply to

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2 approximate number?

MS. SHERER: Objection to form.³

4 A. Yes, there are studies, but I can't
5 quote you the numbers.

6 Q. Do you know the name of any study that
7 would give me approximate risk of death from
8 liver cell cancer for successfully treated --

9 A. Not for successfully. I don't think
10 there is any data on successfully treated
11 patients. That group we talked about
12 previously, I don't believe that there are any
13 long-term studies on that.

14 Q. So, with respect to Mr. Lin, are there
15 any studies which would indicate what his risk
16 of death from liver cell cancer would be?

17 A. Precisely, no.

18. Q. Approximately.

¹⁹ A. No. I don't think anyone can give you a
²⁰ number.

Q. Is the use of the word "significant"
that you're using here strictly anecdotal?

MS. SHERER: Objection to form.²³

A. No, because there are many, many studies reported of people in his situation who have

1 D. Clain, M.D.

2 ethnicity. I believe there are legal issues
3 about this.

4 So, would we test everybody for
5 hepatitis B who's going for insurance? That is
6 an insurance company question for the insurance
7 company. If you ask me, what would I do in my
8 medical office, the answer is different.

9 Q. What would you do in your medical
10 office?

11 A. In my medical office, if someone was an
12 Asian immigrant, if I was a primary care
13 doctor, I would test them for hepatitis B.

14 Q. When would you begin to treat a patient
15 for hepatitis B when using the various test
16 results we have for Mr. Lin?

17 At what numbers? And we could refer to
18 the viral DNA and the E antigen and liver
19 function tests. When would you begin to
20 retreat him?

21 A. First, we'd need to have an elevated DNA
22 level, significantly elevated, which at least
23 in excess of a hundred thousand.

24 Q. Did he have --

25 A. Yes, he had millions.

1 D. Clain, M.D.

2 Q. At any point from looking at the data
3 that you saw, should he have been retreated?

4 A. No.

5 Q. So, from looking at the data that you
6 saw, would you agree that the treatment for the
7 entire time that you had data was successful?

8 A. Medical drug treatment, yes.

9 MR. TRIEF: Let's take a few
10 minutes.

11 (Whereupon, a recess was taken.)

12 Q. You indicated earlier that you don't
13 have any idea whether successfully treated
14 hepatitis B patients in the United States have
15 a lower mortality rate --

16 MS. SHERER: Objection to the
17 form.

18 Q. -- or you do, than people who are not
19 infected?

20 Do you have any idea?

21 A. Sorry. Can you just restate that.

22 Q. I'm sorry. It was my fault. It wasn't
23 your fault.

24 I am talking significantly now. Is
25 there any significant difference in mortality

1 D. Clain, M.D.

2 between a successfully treated hepatitis B
3 patient than the general public?

4 A. Yes, there is a difference between the
5 two.

6 Q. Do you know what it is?

7 A. I don't know.

⁸ You asked me that before.

9 Q. Would you be able to tell if it was
10 significant or insignificant?

11 A. Yes. I believe the numbers for both
12 treated patients and those who never been
13 treated are inactive, but I think they're
14 whatever -- are several times those who are not
15 infected. I can't give you have a number.

¹⁶ Q. But "several times" doesn't measure the
¹⁷ mortality.

18 A. I can't give you the mortality.

19 Q. It's the mortality part I'm talking
20 about.

Let's say the average American lived to
72. The person who is infected, but treated
successfully, would that person live to 65 or
71.3? Would you be able to give me any range?

25 A. Yes. Let me just explain some of the